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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/331,376	06/18/1999	OYSTEIN FODSTAD	7885.65USWO	1579
23552	7590	04/05/2004	EXAMINER	
MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 04/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/331,376	<b>Applicant(s)</b> FODSTAD ET AL.	
	<b>Examiner</b> MINH-TAM DAVIS	<b>Art Unit</b> 1642	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-11 and 13-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-11, 13-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |                                                                                                                        |                                                                                         |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

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### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/15/04 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 1-4, 6-11, 13-17 are being examined.

The following are the remaining rejections.

### **REJECTION UNDER 35 USC 103**

Rejection under 35 USC 103 of claims 1-4, 6-11, 13-17 pertaining to remains for reasons already of record in paper of 07/15/03.

Applicant argues that Hajek et al do not teach "each antibody of the 2 to 6 antibodies is conjugated to different particles".

Applicant argues that Fodstad et al are directed to providing of increasing the specificity, and thus one would recognize that for increasing specificity, the second set of antibodies would be directed to the same cells as the antibody-particle complexes. Applicant asserts that thus Fodstad et al teach a single type of antibody-particle complex for detecting a single type of target cell.

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Applicant asserts that O'briant does not cure the deficiency of Hajek et al and Fodstad et al.

Applicant's arguments set forth in paper of have been considered but are not deemed to be persuasive for the following reasons:

It is noted that the claims are drawn to a method to detect and phenotype target cells in cell suspensions by using particles coated with "antibodies" directed against "antigenic determinants/receptors" expressed on the target cells. Thus the claims do not exclude that the second set of antibodies could be directed to the same type of cells as the first antibody-particle complex.

Further, different from Applicant interpretation, since Fodstad et al are directed to providing of increasing the specificity, one would recognize that for increasing specificity, the second set of antibodies would be directed to a different type of cells as the first antibody-particle complexes, to distinguish different type of cells, thus increasing the specificity.

In addition, although Hajek et al do not specifically teach "each antibody of the 2 to 6 antibodies is conjugated to different particles", Hajek et al teach that the cells are combined with a plurality of sets of microspheres, each set having a reactant (antibody) bound specifically to a different specific molecule on at least one type of cell (claim 18).

Further, O'briant et al teach that use of multiple monoclonal antibodies can compensate for the heterogeneity of antigenic phenotype within and between tumors (p.1276).

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Thus it would have been obvious to use the method of Hajek et al, in which a plurality of sets of microspheres, each set having a reactant (antibody) are bound specifically to a different specific molecule on at least one type of cell. It would have been obvious to include at least 2 antibodies in the plurality of sets of microsphere-antibody complexes taught by Hajek et al, because of the following reasons: 1) a plurality means at least two, which is within the range of the number of the antibodies used in the claimed method, and 2) Fodstad et al teach the use of a second set of antibody against the tumor cells.

One of skill in the art would have been motivated to use the method of Hajek et al in combination with Fodstad et al to phenotype within and between tumors, as taught by O'briant et al, and Hajek et al, with a reasonable expectation of success.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, YVONNE EYLER can be reached on 703-308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

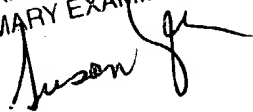
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

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SUSAN UNGAR, PH.D.  
PRIMARY EXAMINER

A handwritten signature in black ink, appearing to read "Susan", written over the printed name of the primary examiner.

MINH TAM DAVIS

March 29, 2004